sample required hereunder which includes such material as an ingredient or component of an ingredient, unless and until the person requesting certification makes an adequate showing that the cause for such refusal no longer exists.

[39 FR 11750, Mar. 29, 1974, as amended at 39 FR 40286, Nov. 15, 1974; 44 FR 48968, Aug. 21, 1979; 44 FR 55170, Sept. 25, 1979; 45 FR 40111, June 13, 1980; 50 FR 8996, Mar. 6, 1985; 55 FR 11582, Mar. 29, 1990]

§ 429.41 Certifications.

(a) If it appears to the Commissioner, after such investigation as he considers necessary, that:

(1) The information (including results of tests and assays) and the samples required by or pursuant to § 429.40 have been submitted, and such information contains no untrue statement of a material fact;

(2) The batch complies with the regulations in this part 429 and conforms to the standards of identity, quality, strength, and purity for insulin injection, protamine zinc insulin suspension, globin zinc insulin injection, isophane insulin suspension, insulin zinc suspension, prompt insulin zinc suspension, or extended insulin zinc suspension;

the Commissioner shall certify that such batch is safe and efficacious for use, subject to such conditions on the effectiveness of such certifications as are set forth in § 429.45, and shall issue to the person who requested it a certificate to that effect.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that the information submitted pursuant to § 429.40 or the batch covered by such request, does not comply with the requirements set forth in paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who requested certification, stating his reasons for refusal.

(c) Upon the request of the manufacturer, the Commissioner shall certify as a ''batch'' a master lot, which has been approved in accordance with § 429.40(j) as safe and efficacious for use in preparation of an insulin-containing drug, subject to the conditions on the effectiveness of such certifications as are set forth in § 429.45(a) (1) and (b) (4).

(d) For the purposes of his investigations under the authority of this section, the Commissioner may accept, when he is satisfied as to the completeness and accuracy thereof, the results of any tests or assays made by the control laboratory of the Insulin Committee of the University of Toronto.

§ 429.45 Conditions on the effectiveness of certificates.

(a) A certificate shall not become effective:

(1) If it is obtained through fraud, or through misrepresentation or concealment of a material fact.

(2) With respect to any package, unless its immediate container complies with the requirements of § 429.10 and such package or such immediate container has been so sealed that its contents cannot be used without destroying such package or seal.

(3) With respect to any package, unless its label and labeling bear all words, statements, and other information, and are distinguished by the color or colors, required by §§ 429.11 and 429.12.

(b) A certificate shall cease to be effective: (1) With respect to any package of insulin injection, protamine zinc insulin suspension, globin zinc insulin injection, isophane insulin suspension, insulin zinc suspension, prompt insulin zinc suspension, or extended insulin zinc suspension on the expiration date specified in the U.S.P.

(2) With respect to any package, when such package or the seal thereof or the immediate container therein or the seal of the immediate container is broken, or when its label or labeling ceases to conform to any requirement of § 429.11 or § 429.12.

(3) With respect to any package, when the drug therein so changes that it fails to meet the standards of identity, strength, quality, and purity upon the basis of which the batch was certified; except that those minor changes in potency (not exceeding 10 percent from the potency stated on the label, in the case of insulin injection) which occur before the expiration date, and which are normal and unavoidable in

good storage and distribution practice, shall be disregarded.

(4) With respect to a master lot of insulin, 5 years after date of issue if the master lot is a solution, or 10 years after date of issue if the master lot is a solid.

[39 FR 11750, Mar. 29, 1974, as amended at 39 FR 40286, Nov. 15, 1974]

§429.47 Authority to refuse certification service.

When the Commissioner finds, after giving notice and opportunity for hearing, that a person has:

(a) Obtained or attempted to obtain a certificate through fraud, or through misrepresentation or concealment of a material fact;

(b) Falsified the records required to be kept by §429.60; or

(c) Failed to keep such records or to make them available, or to accord full opportunity to make an inventory of stocks on hand or otherwise to check the correctness of such records, as required by such section;

the Commissioner may immediately suspend service to such person under the regulations in this part, and may continue such suspension unless and until such person shows adequate cause why such suspension should be terminated.

Subpart F—Administrative Procedures

§429.50 Hearing procedure.

Hearings pursuant to §429.47 shall be governed by part 16 of this chapter.

[41 FR 48267, Nov. 2, 1976, as amended at 42 FR 15674, Mar. 22, 1977]

§429.55 Fees.

(a)(1) Fees for the services rendered under the regulations in this part shall be such as are necessary to provide, equip, and maintain an adequate certification service.

(2) Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged.

(b) The fees for requests for certification submitted under §429.40 are as follows:

(1) $2,400 for each master lot or mixture of two or more master lots or parts thereof.

(2) $1,700 for each dosage form batch.

(3) The fees established in this paragraph may increase as Federal salary costs increase. The rate of increase will be no higher than Federal salary increases, commencing with pay raises on or after January 1, 1997. Notification of the exact fees established and adjustments will be communicated directly to the manufacturers of insulin products.

(c) A person requiring continuing certification services may maintain an advance deposit of the estimated costs of such services for a period of 2 months or more. Such deposits shall be debited with fees for services rendered, but shall not be debited for any fee the amount of which is not definitely specified in these regulations unless the depositor has previously requested the performance of the services to be covered by such fee. A monthly statement for each such advance deposit shall be rendered.

(d) The unearned portion of any advance deposit made pursuant to paragraph (b) or (c) of this section shall be refunded to the depositor upon his application.

(e) All advance deposits required by the regulations in this part 429 shall be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectible at par at Washington, DC. All deposits shall be forwarded to the Food and Drug Administration, Department of Health and Human Services, Washington, DC 20204, whereupon after making appropriate record thereof they will be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasurer of the United